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July 27, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

SUBJECT: Docket 98N-1215
Proposed Rule: Foreign Establishment Registration and Listing

Dear Sir or Madam:

We refer to your May 14, 1999 Federal Register notice requesting comments on proposed rule "Foreign Establishment Registration and Listing," Docket No. 98N-1215. We appreciate the opportunity to provide comments, which include input from our colleagues at our world headquarters in Beerse, Belgium. The following comments are provided (in bold face type) for your consideration.

Section II.A.1.b./Proposed changes to Section 207.40 (c), "Each foreign drug establishment shall designate only one United States agent."

The requirement, under Section 207.40 (c), that the establishment designate only one United States Agent, may place the establishment or the importing firm at a competitive disadvantage and jeopardize their proprietary interests. A foreign establishment may have several distributors in the United States, acting independently and possessing distinct proprietary and business interests. As pointed out by the FDA in its discussion of revised Section 207.40 (c), FDA disclosure, to one of the distributors, of confidential commercial information or trade secrets, or issues related to the other distributors' interests, would violate the foreign establishment's proprietary and business interests. A conflict of interest may be created for the United States Agent, making it difficult to properly execute the duty of agent for the foreign establishment. FDA's interest in enhanced communication and the rapid acquisition of information from the foreign establishment would best be served by allowing the foreign establishment to determine, according to business and proprietary needs, the number of agents needed for effective representation in the United States.

Section II.E.: Registration Schedules, "In general, the registration schedule would be similar in concept to Section 207.21 whereby firms whose name began with a particular letter of the alphabet would register within a specific month."

This proposal does not take into account the capacities and administrative logistics of the establishment in a given month, particularly if the establishment must register immediately due to the alphabetical registration schedule. This proposal would also put an undue burden on the importer to assure foreign establishment compliance if the schedule calls for immediate registration. Consider also the implications of company mergers or name changes, and the burden of complying with a new registration schedule. Finally, how will manufacturers of multiple product types be handled?

We again thank the Agency for the opportunity to comment on this proposed rule and look forward to a continuing dialog as the Agency finalizes the rule. Please contact me at (609) 730-3081 if you have any questions.

Sincerely,

Sheila Alexander

Assistant Director, Technical Regulatory Affairs

98N-1215

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